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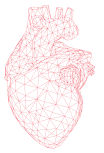
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## Transatrial Implantation of the Sapien 3 Heart Valve in Severe Mitral Annular Calcification: Multi-Clinic Experience, Written and Video Description

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### ABSTRACT

There is growing interest in using transcatheter valve therapy to address mitral valve disease in the setting of severe mitral annular calcification (MAC). Using the Sapien XT or Sapien 3 transcatheter heart valve has produced promising results when implanted from a percutaneous transseptal approach and from a surgical transatrial approach. However, there is lack of technical support for these cases from the transatrial side. Our group has a large experience using the Sapien valve for this purpose and have used a specific technique with excellent results. Here we present a step-by-step presentation of the technique in video detail.

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**KEYWORDS** Transcatheter; transcatheter aortic valve replacement; mitral; mitral annular calcification; mitral valve replacement

### Introduction

There is growing interest in using transcatheter valve therapy to address mitral valve disease in the setting of severe mitral annular calcification (MAC). Using the Sapien XT or Sapien 3 transcatheter heart valve has produced promising results when implanted from a percutaneous transseptal approach and from a surgical transatrial approach. However, there is lack of technical support for these cases from the transatrial side. Our group has a large experience using the Sapien valve for this purpose and have used a specific technique with excellent results. Here we present a step-by-step presentation of the technique and a Supplemental video.

### Clinical vignette

A 78-year-old female with hypertension, paroxysmal atrial fibrillation, mild lung disease and chronic diastolic heart failure was found to have severe mitral stenosis (MS) during a workup for palpitations, dyspnea on exertion, and increased lower extremity edema. Preoperative transesophageal echo (TEE) revealed left ventricular ejection fraction (LVEF) of 65% with severe MS and severe mitral annular calcification (MAC) in the setting of mild mitral regurgitation (MR) and no other significant valvulopathies. Smallest mitral valve area was 1.2 cm<sup>2</sup>, highest mean gradient was 7 mmHg, and the septal dimension was 1.7 cm. The severity of MAC precluded a standard

mitral valve replacement (MVR) due to the inability and risk of placing sutures into the calcium. Therefore, the patient was offered a transatrial deployment of a Sapien 3 transcatheter valve (S3) into the native mitral valve, avoiding the need for calcium debridement.

### Surgical technique

#### Preparation

Pre-operatively, a mitral-protocol multi-detector computed tomography scan with intravenous contrast is performed (ECG-gated, multi-phase 0–95% with slice thickness < 1.25 mm at 5–10 mm increments). Reconstruction of the mitral annulus is performed using 3Mensio software (3Mensio Structural Heart Mitral Workflow version 8.1 Pie Medical Imaging, Maastricht, the Netherlands). The mitral annulus is traced using multi-planar reconstruction to obtain systolic and diastolic phase dimensions, area, and perimeter; diastolic measurements are used for valve sizing, while systolic measurements are used for left ventricular outflow tract (LVOT) obstruction risk analysis. The “neo-LVOT” or predicted LVOT area after valve implantation is modeled using a virtual valve positioned at the annular level, and the residual area not occupied by the valve frame is calculated. High risk for LVOT obstruction is predicted at an area less than 150 mm<sup>2</sup>. This information helps to inform about suitability for a percutaneous approach and possible need for septal myectomy. Finally,



an aortomitral angle of greater than 120° may also pose additional risk for LVOT obstruction.

In the operating room, the patient is positioned and draped for a traditional full median sternotomy approach. In a routine fashion, sternotomy is preformed, activated clotting time (ACT)-guided heparinization is instituted, and the ascending aorta, superior vena cava (SVC), and inferior vena cava (IVC) are cannulated. After placement of the antegrade cardioplegia catheter, cardiopulmonary bypass is begun and the patient cooled to 32°C. After application of the aortic crossclamp, Del Nido blood cardioplegia is delivered antegrade.

### Exposition

The left atrium is vented through a stab wound and the left atrial appendage is then ligated with an Atriclip (AtriCure, Mason, OH, USA). The left atrium is opened posterior to the interatrial groove. Adequate exposure of the valve is obtained using the handles for the Cosgrove rack and retractor (Kapp Surgical Instrument Inc., Cleveland, OH, USA). As expected, inspection of the mitral valve reveals severe MAC throughout the annulus. The valve leaflets are immobile and foreshortened, and the chordae are completely fused with the papillary muscles.

### Operation

Due to concern for residual LVOT obstruction even with anterior mitral leaflet resection due to septal thickness, a septal myectomy is planned. A septal myectomy is performed prior to valve replacement by making an oblique aortotomy in the aorta. A 4–0 prolene is placed in the septal muscular tissue below the conduction tissue and a #15 blade is used to remove a 3 × 2 × 2 cm piece of septal muscular tissue. The aorta is closed with a running 4–0 suture.

The anterior leaflet is resected, leaving a 1-cm rim of tissue, while the posterior leaflet is left intact. The lateral head of the papillary muscle is partially resected and the chordae are divided to provide more room for the transcatheter valve to expand and avoid interference. The valve orifice opening is sized using the 26 mm Edwards Sapien 3 delivery balloon (Edwards Lifesciences Corp., Irvine, CA, USA). Of note, the annulus is also sized by intraoperative TEE and preoperative gated, multidetector computed tomography, both of which confirmed a 26 mm valve size. A balloon that fits snugly within the annulus at nominal or close to nominal valve volume suggest appropriate sizing; a balloon that slides easily or is significantly underinflated suggests that a larger or smaller valve sized should be used, respectively.

The Sapien 3 valve (Edwards Lifesciences Corp., Irvine, CA, USA) is prepared on the back table by sewing a soft felt skirt of 1 cm height to the Sapien 3 frame and skirt at the base (atrial side) using a running 5–0 suture, which is tied on each end to the valve frame so that the frame expansion is not constrained. Care is taken to avoid suturing through Sapien leaflet tissue. The valve is then directly crimped on the 26 mm Edwards Certitude transthoracic delivery system, after marking the strut commissures with a marking pen.

Then, 2–0 Tevdek pledgeted sutures (Teleflex Medical, Triangle Park, NC, USA) are placed circumferentially through

the anterior and posterior leaflet tissue with pledgets on the atrial side, with the intention of further reducing paravalvular leak. The valve system is then directly introduced into the left atrium over a soft J-wire, with care taken to position the valve extending 2 mm on the atrial side as final position and orienting the marked commissures to avoid the LVOT before deploying it with full volume balloon. Deployment is performed as a two-person procedure with close coordination between the positioning operator and the inflating operator. Attempts to keep coaxiality between the mitral annular plane and the Sapien 3 valve are made with the use of forceps. Inflation is slow, controlled and deliberate; consideration of motion is given to the normal foreshortening of the Sapien 3 frame. All anchoring sutures are then placed through the valve frame and felt skirt and tied down. The valve is then post-dilated with the same delivery system balloon with an extra 2 cc of volume. There are no major leaks on testing. In addition, an ablation procedure using endocardial cryo-ablation is then performed.

### Completion

Atriotomy is closed with running 3–0 prolene. In the usual fashion, the heart is de-aired by applying high suction to the aortic root vent, aortic clamp is released and organized rhythm is restored. The valve function appeared good on echo with no MR or paravalvular leak (PVL), with a post aortic-LVOT gradient of 3–4 mm (unchanged from preoperative). After further standard de-airing maneuvers, the aortic vent is removed. Two right ventricular pacing wires are attached, as well as placing a 28Fr chest tube in the anterior mediastinum, a 19Fr Blake tube in the inferior mediastinum, and tubes in the pleura. The patient is gradually weaned from cardiopulmonary bypass. After protamine and decannulation, the pericardium is closed with absorbable suture. The sternum is closed with surgical steel wires and the chest is closed in the usual fashion. Warfarin is continued for 3 months postoperatively.

### Comments

#### Clinical results

In a collaboration of six North American centers, a total of 26 patients with symptomatic mitral valve disease and severe MAC have undergone direct transatrial implantation of a transcatheter heart valve (THV) between April 2015 and September 2017<sup>1</sup> using the same technique. The mean age of the patients was 78 ± 7 years and the mean Society of Thoracic Surgeons (STS) score predicted mortality risk for MVR was 9.45 ± 4.89%.<sup>1</sup> Except for one patient, who had a right thoracotomy, median sternotomy as described above was performed in all patients. Two patients (8%) received an Edwards Sapien XT, while 24 (92%) received an Edwards Sapien 3 valve. Technical success according to the MVARC criteria was achieved in all patients (100%).<sup>1</sup> Five patients died during hospital stay (19%), and among the 21 patients discharged alive, 11 had no or trace residual MR, with another 10 patients having mild residual MR.<sup>1</sup>



### Advantages

Our experience has demonstrated that direct surgical transatrial implantation of a Sapien THV for treatment of severe MAC can be performed with high technical success and with very low incidence of PVL. As opposed to transseptal or transapical deployment of THV, direct transatrial approach enables systematic resection of the anterior mitral valve leaflet, thus allowing for safe treatment of patients at high risk for LVOT obstruction. In addition, it also allows for precise balloon sizing, evaluation of anchoring, placement of pledgeted sutures leaflet tissue to reduce PVL, while also addressing the non-circumferential annular calcification that would increase the risk of valve embolization in a transseptal or transapical approach. In contrast to standard techniques for MAC which substantially increase the risk of bleeding or posterior atrioventricular groove disruption, the use of a balloon expandable THV avoids the need for extensive debridement of subvalvular apparatus calcifications, while minimizing the risk of PVL.

### Limitations

Several steps have been implemented and the procedure modified since it was originally reported.<sup>2</sup> Notably, in patients with severe MAC, risk of PVL is increased due to the irregular anatomy of the annular calcium rim, so we

suture a soft felt strip to the inflow part of the stent valve frame in order to optimize valve apposition. In addition, we place several pledgeted sutures along the residual leaflet tissue to help reduce PVL. Other technical tips include the use of balloon sizing intraoperatively to confirm final valve size, very slow valve inflation, first operator positioning to ensure atrial location on the sealing zone, and removal of chordae and even papillary muscle to allow proper space in the ventricle for the valve to expand.

### Disclosure statement

Issac George is a consultant for Edwards Lifescience and Medtronic. Vinayak Bapat is a consultant to Edwards Lifesciences, Medtronic Inc, Abbott, 4Tech and Boston Scientific. Dr Borger has received speaking fees from Edwards Lifesciences. The remaining authors declare no conflict of interest related to this work.

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